Urgent

中国 WTO/TBT 国家通报咨询中心

China WTO/TBT National Notification Authority & Enquiry Point

No.7, Ma Dian Dong Ave, Hai Dian District, Beijing, China, Tel: 86 10 8226 0618 Fax:86 10 8226 2448

TO:	Fumie Yokota Desk Officer for FDA Office of Information and Regulatory Affairs, OMB	**Tel:** **Fax:**	+ (1 202-395-6974, + (1 301-827-6870
		E-mail:	fdadockets@oc.fda.gov
		Page:	4 (inc. this page)

Aus.6, 2004

Subject: Docket No. 2004N-0257

Request for Extension of Deadline

Dear Sir or Madam:

As for your notification of G/TBT/N/USA/67 and its addendum G/TBT/N/USA/67/Add.1, the final dates for comments are different. Please kindly clarify whether it is August 13 or October 12. If the deadline date for comments is August 13, we hope you can prolong it to the date of October 12, 2004, so that we could have enough time for making comments.

We'll be grateful if you acknowledge receiving this request. Thank you.
Your consideration and favorable reply will be very much appreciated.

Best regards,

Guo Lisheng

Guo Lisheng
Deputy Director General

2004N-0257 EXT 1

WORLD TRADE ORGANIZATION

G/TBT/N/USA/67
19 July 2004

(04-3076)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	**Member to Agreement notifying:** UNITED STATES **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Food and Drug Administration (72) **Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Cosmetics and Human Food (HS Chapters 33 and 2106) (ICS 67.020 and 71.100)
5.	**Title, number of pages and language(s) of the notified document:** Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle (10 pages, in English)
6.	**Description of content:** The Food and Drug Administration (FDA) is proposing to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. This is a companion rulemaking to FDA's interim final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics," published in this issue of the Federal Register. FDA is proposing recordkeeping requirements because records documenting the absence of prohibited cattle materials are needed by manufacturers and processors of human food and cosmetics that contain cattle material to ensure that these products do not contain prohibited cattle materials. In addition, such records are necessary to help FDA ensure compliance with the requirements of the interim final rule.
7.	***Objective and rationale, including the nature of urgent problems where applicable:*** Protection of human health.
8.	**Relevant documents:** 69 Federal Register (FR) 42275 14 July 2004; Title 21 Code of Federal Regulations (CFR) Parts 189, and 700. Will appear in the Federal Register when adopted.
9.	**Proposed date of adoption:** **Proposed date of entry into force:** } To be determined

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WORLD TRADE ORGANIZATION

G/TBT/N/USA/67/Add.1
21 July 2004

(04-3150)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 16 July 2004, is being circulated at the request of the delegation of the United States.

Use of Materials Derived From Cattle in Human Food and Cosmetics; and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle; Final Rule and Proposed Rule

The Food and Drug Administration (FDA) is issuing an interim final rule (interim final rule) to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS)(Beef). Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. FDA is taking this action in response to the finding of an adult cow, imported from Canada, that tested positive for BSE in the State of Washington. This action is consistent with the recent interim final rule issued by the U.S. Department of Agriculture (USDA) declaring specified risk materials and the carcasses and parts of non-ambulatory disabled cattle to be inedible, unfit for human food, and prohibiting their use as human food and requiring that the entire small intestine be removed and disposed of as inedible. This action will minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. Also in this issue of the Federal Register, FDA is proposing to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain material from cattle establish and maintain records sufficient to demonstrate that the food and cosmetics are in compliance with this interim final rule.

DATES: The interim final rule is effective on July 14, 2004. Submit written or electronic comments by October 12, 2004. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 189.5 and 700.27 as of July 14, 2004.

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ADDRESSES: You may submit comments, identified by Docket No. 2004N-0081, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov.
Follow the instructions for submitting comments on the agency Web site.

E-mail. fdadockets@oc.fda.gov.
Include Docket No. 2004N-0081 and or RIN number RIN-0910-AF47 in the subject line of your e-mail message.
FAX: 301-827-6870.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to http://www.fda.gov/dockets/ecomments, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see section V in the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.fda.gov/dockets/ecomments and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Rebecca Buckner,
Center for Food,
Safety and Applied Nutrition (HFS-306),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740,
301-436-1486.
